

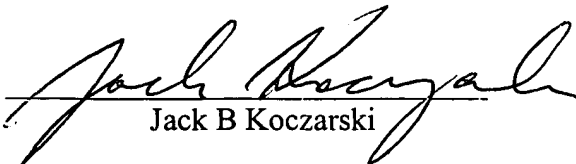


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Date: 9/1, 2004


Jack B Koczarski

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of:

Zaczek et al.

CASE NO.: BMS- PH-7048-A(C)

APPLICATION NO.: 10/734,031

GROUP ART UNIT: 1616

FILED: December 11, 2003

EXAMINER: TBD

FOR: Use of Small Molecule Radioligands to Discover Inhibitors of Amyloid-Beta Peptide
Production and for Diagnostic Imaging.

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b). Copies of the references listed on Form PTO/SB/08A pages 1-of 5, 2 of 5 and 3 of 5 and 4 of 5 are attached except US patents. Copies of references #66, #72 and those listed on page 5 of 5 are not provided. References #66 and #72 will be provided if requested by the examiner. The references listed on page 5 of 5 were previously cited by or submitted to the office in a prior application Serial No. 09/438,901 filed November 12, 1999 and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

- () In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on

the merits of the above-identified application, no additional fee is required. The Commissioner is authorized to charge any fees required to Deposit Account No. 03-3975.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

() Certification in Accordance with §1.97(e) is set forth below.

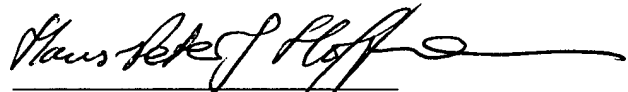
() The fee of _____ as set forth in §1.17(p) is attached.

- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$____ as set forth in §1.17(p).

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There are no listed references which are not in the English language or do not contain an English language abstract.

Respectfully submitted,



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PTO/SB/21 (02-04)

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Application Number	10/734,031	
	Filing Date	December 11, 2003
	First Named Inventor	Zaczek
	Art Unit	1616
	Examiner Name	TBD
Attorney Docket Number	BMS-PH-7048-A(C)	
Total Number of Pages in This Submission		

ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please Identify below): 1. PTO/SB/08A 2. 53 References
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Hans- Peter G. Hoffmann, Reg. No. 37,352
Signature	
Date	September 1, 2004

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) NONE

Complete if Known

Application Number	10/734,031
Filing Date	December 11, 2003
First Named Inventor	Zaczek
Examiner Name	TBD
Art Unit	1616
Attorney Docket No.	BMS-PH-7048-A(C)

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☒ Other ☐ None

☒ Deposit Account:

Deposit
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03-3975

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims	Fee from below	Fee Paid
Total Claims	-20** =	X	
Independent Claims	-3** =	X	
Multiple Dependent			

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

Name (Print/Type)	Hans- Peter G.Hoffmann	Registration No. (Attorney/Agent)	37,352	Telephone	203 965-8271
Signature	<i>Hans Peter G. Hoffmann</i>	Date	September 1, 2004		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

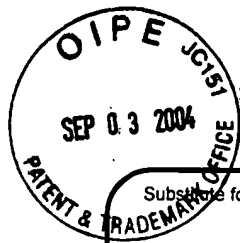
Application Number	10/734,031
Filing Date	December 11, 2003
First Named Inventor	Zaczek
Group Art Unit	1616
Examiner Name	TBD
Attorney Docket Number	BMS-PH-7048-A(C)

US PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Issue Date	Name	Class	Sub Class	FILING DATE If Appropriate
	1	5,506,242	04/09/1996	MacPherson et al.			
	2	5,538,845	07/23/1996	Knops et al.			
	3	5,552,419	09/03/1996	MacPherson et al.			
	4	5,593,846	01/14/1997	Schenk et al.			
	5	5,594,006	01/14/1997	Sakamoto et al.			
	6	5,672,598	09/30/1997	De et al.			
	7	5,734,054	03/31/1998	Dolle, III et al.			
	8	5,703,129	12/30/1997	Felsenstein et al			
	9	5,942,400	08/24/99	Anderson et al			
	10	5,766,846	06-1998	Schlossmacher et al			
	11	6,737,038	05/18/2004	Zaczek at al			
	12	6,331,408	12/18/2001	Zaczek et al			
	13	5,604,102	02-1997	McConnlogue et al.			
	14	5,744,346	04-1998	Chrysler et al			
	15	6,329,163	12-2001	Anderson et al.			
	16	5,843,941	12/1/98	Marsters et al			
	17	5,532,359	7/2/96	Marsters et al.			
	18	5,721,106	02/1998	Maggio et al.			

FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No	
	19	WO-95/09838	04/13/1995	Cordell et al.				
	20	WO 96/29313	09/26/1996	Wahl et al.				
	21	WO 98/22493	05/28/1998	Thorsett et al.				
	22	WO-98/22494	05/28/1998	Audia et al.				
	23	WO 98/28268	07/02/1998	McDaniel et al.				
	24	WO-98//38177	03/09/1998	Thorsett et al				
	25	WO 99/66934	12/29/1999	Audia et al.				
	26	WO-99/67219	12/29/1999	Elan Pharmaceuticals Inc.				



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Sheet 2 of 5

Application Number	10/734,031
Filing Date	December 11, 2003
First Named Inventor	Zaczek
Group Art Unit	1616
Examiner Name	TBD
Attorney Docket Number	BMS-PH-7048-A(C)

FOREIGN PATENT DOCUMENTS

27	WO-99/67220	12/29/1999	Elan Pharmaceuticals Inc.				
28	WO 99/67221	12/29/1999	McDaniel et al.				
29	WO 00/24392	05/04/2000	Ito et al.				

OTHER ART

(including Author, Title, Date, Pertinent Pages, Publication, Etc.)

30		A. Ahmed et al., <i>FEBS Letters</i> , (1984), vol.174, pp. 76-79
31		Arora et al., <i>J. Med. Chem.</i> , 30: p.918 (1987)
32		P. Becket, M. J. Crimmin, M. H. Davis, and Z. Spavold, <i>Synlett</i> (1993), pp. 137-138
33		Bock et al., <i>J. Med. Chem.</i> 1993, 36, pp.4276-4292.
34		Bock et al., <i>J. Org. Chem</i> 1987, 52, pp. 3232-3239
35		F. A. Carey and R. J. Sundberg, "Advanced Organic Chemistry, Part A," <i>New York: Plenum Press</i> , 1990, pp. 304-305, 342-347, 475-479, 695-698
36		Chumpradit et al., <i>J. Med. Chem.</i> , 32: p. 1431 (1989)
37		Chumpradit et al., <i>J. Med. Chem.</i> , 34: p. 877 (1991)
38		Ellis et al., <i>Aust. J. Chem.</i> , 26,: p. 907 (1973)
39		Evans, A et al. <i>Org.Synth.</i> 68.p83-91 (1990)
40		Glenner and Wong, <i>Biochem. Biophys. Res. Commun.</i> 120; pp.885-890
41		Ghosh et al. <i>JACS</i> (2000) 122 pp.3522-3523
42		J. Higaki, D. Quon, Z. Zhong, B. Cordell, "Inhibition of beta-amyloid Formation identifies Proteolytic Precursors and Subcellular Site of Catabolism", <i>Neuron</i> 14, pp. 651-659, 1995
43		Jacobson and Reddy, <i>Tetrahedron Letters</i> , Vol 37, No. 46, pp.8263-8266
44		Kabalka et al., <i>J. Label. Compound. Radiopharm.</i> , 19: p. 795 (1982)
45		A. S. Kende et al., <i>Tetrahedron Lett.</i> 1989, 30 (43), 5821-5824
46		K. S. Kirshenbaum, K. B. Sharpless, <i>J. Org. Chem.</i> (1985), 50 (11), pp. 1979-1982



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 5

Application Number	10/734,031
Filing Date	December 11, 2003
First Named Inventor	Zaczek
Group Art Unit	1616
Examiner Name	TBD
Attorney Docket Number	BMS-PH-7048-A(C)

OTHER ART

(including Author, Title, Date, Pertinent Pages, Publication, Etc.)

47	P. Kocienski, <i>Tetrahedron</i> 1990, 46, pp. 1767-1782
48	Koch et al., <i>Chem. Ber.</i> , 124: p. 2091 (1991)
49	Levitan, D. and Greenwald, I. <i>Nature</i> , 377, pp 351-354, 1995
50	Lin et al., <i>PNAS</i> (2000) 97: pp. 1456-1460.
51	Mach et al., <i>J. Med. Chem.</i> , 1993, 36, pp. 3707-3720
52	McClure and Axt, <i>Bioorganic & Medicinal Chemistry Letters</i> , 8 (1998), pp. 143-146
53	Merkushev, <i>Synthesis</i> , 923 (1988)
54	C. F. Nutaitis and M. W. Ledeboer, <i>Org. Prep. Proced. Int.</i> (1992), 24 (2), pp. 143-146
55	Pratt et al., <i>Synlett</i> , May 1998, p. 531
56	M. P. Reddy and P. J. Voelker, <i>Int. J. Pept. Protein Res.</i> 1998, 31, pp. 345-348
57	"Remington's Pharmaceutical Sciences," 17 th ed. Mack Publishing Company, Easton, PA, 1985, p. 1418.
58	D. J. Selkoe, "Cell Biology of the amyloid (beta)-protein precursor and the mechanism of Alzheimer's disease," <i>Annu. Rev. Cell. Biol.</i> , 1994, 10: pp 373-403
59	Seevers et al., <i>Chem. Rev.</i> , 82, p. 575 (1982)
60	Sherrill and Sugg, <i>J. Org. Chem.</i> 1995, 60, pp. 730-734
61	Vassar et al., <i>Science</i> 1999 286: pp. 735-741
62	D. A. Walsh, <i>Synthesis</i> , September 1980, p. 677
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65	Wolf, Chrisman, Fowler, Lambrect, "Synthesis of Radiopharmaceuticals and Labeled Compounds Using Short-Lived Isotopes," in <i>Radiopharmaceuticals and Labeled Compounds</i> , Vol. 1, 1973, pp. 345-381.



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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5

Application Number

10/734,031

Filing Date

December 11, 2003

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Zaczek

Group Art Unit

1616

Examiner Name

TBD

Attorney Docket Number

BMS-PH-7048-A(C)

OTHER ART

(including Author, Title, Date, Pertinent Pages, Publication, Etc.)

66	Book	M.Keen (ed) Receptor binding techniques methods in molecular Biology, Vol 106, Humana Press, Totowa, New Jersey, 1999
67		Eckelman et al. J.Nucl. Med, Vol. 20(4) pp.350-357 (1979)
68		T.W.Green and Wuts, Protective Groups in organic Synthesis (Wiley 1991)
69		Tubis and Wolf, eds Radiopharmacy, Wiley-Interscience New York (1976) Vol 1 p.345-381(1973)
70		Wilson et al. J.Org.Chem 51 4833 (1986)
71		U.S. Pharmacopia-The National Formulary 22 nd Revision, Mack Printing Co. Easton, Pa 1990. "Radioactive Pharmaceuticals" relevant sections as per Index on page 2049
72	Book	A. Macowski Medical Imaging Systems ed. Prentice-Hall, Inc Englewood Cliffs NJ(1983)
73		E.I. Rogaev et al. Nature, Vol 376 pp 774-778 (1995)



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet

5

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5

Application Number

10/734,031

Filing Date

December 11, 2003

First Named Inventor

Zaczek

Group Art Unit

1616

Examiner Name

TBD

Attorney Docket Number

BMS-PH-7048-A(C)

FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No
	74	WO 95/22966	08/31/1995	Mathiowetz et al.			
	75	EP0652009	05/10/1995	Dovey et al.			
	76	EP0276436	12/10/1987	Broadhurst et al.			
	77	EP0606046	12/21/1993	MacPherson et al.			
	78	WO 92/00374	01/09/1992	Nelson Et al.			
	79	WO 92/06966	04/30/1992	Markwell et al.			
	80	WO 98/15828	04/16/1998	Cordell et al.			
	81	WO-00/28331	05-2000	Zaczek et al.			

OTHER ART

(including Author, Title, Date, Pertinent Pages, Publication, Etc.)

82		M. G. Natchus et al., "Design and synthesis of conformationally constrained MMP inhibitors," Chemical Abstracts, vol. 129, no. 22, 30 November 1998, abstract no. 290051p.
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Examiner
SignatureDate
Considered

¹ EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ² Unique citation designation number. ³ See attached Kinds of U.S. Patent Documents. ⁴ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁵ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁷ Applicant is to place a check mark here if English language Translation is attached.

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